"BUYING INNOVATIVE"

IN THE HEALTHCARE BIOTECH MARKET IN EUROPE

EuropaBio®

The European Association for Bioindustries

1. SCOPE AND OBJECTIVES

The 2006 Aho Report on Creating an Innovative Europe stated that public procurement offers opportunities to drive innovation by creating innovation-friendly markets, while at the same time improving the level of public services[1]. The adoption of the new European legislative package for public procurement in February 2014 established a more efficient and flexible framework for the public procurement of goods, works and services across the Union.

Building on this perspective, the objective of this briefing paper is to describe how the sound use of public procurement can drive demand for and provision of innovative biological medicines. Ultimately it aims to identify how institutions and purchasing authorities can facilitate competitive market demand for healthcare innovation in Europe.

This paper proposes key steps to consider when purchasing biological medicines, looking at each stage of the procurement process. It builds on the examples collected in the 2015 EuropaBio White Paper on Public Procurement of Biological Medicines[2] and includes additional evidence and best practices for purchasing authorities to use as needed and appropriate.

2. DIRECTIVE 2014/24/EU: PRO-INNOVATION PROVISIONS FOR THE HEALTHCARE BIOTECHNOLOGY SECTOR

Directive 2004/18/EC on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts[3] – later on repealed by directive 2014/24/EU[4] on public procurement – supported the elimination of barriers to the freedom to provide services and goods, and therefore to protect the interests of economic operators established in a Member State, who wish to offer goods or services to contracting authorities established in another Member State.

Since the adoption of directive 2004/18/EC, public procurement rules have increasingly been applied to healthcare products. While it is recognised that the application of public procurement rules to the healthcare sector has led to budget savings[5], no systematic review of the application of directive 2004/18/EC for the healthcare sector has been conducted.

The revised EU directive on public procurement (directive 2014/24/EU) focuses on implementing the EU's growth strategy – Europe 2020 – which aims to ensure that the European economy is based on sustainable growth, fostering innovation and social inclusion. Investing in health contributes to the Europe 2020 objectives: health is a value in itself and a precondition for economic prosperity. People's health influences economic outcomes in terms of productivity, labour supply, human capital, social cost and public spending. The transposition of the new public procurement rules is an opportunity to provide Member States with guidance on optimal purchase of biological medicines which, on the long term, would result in a triple win for i) patients' access to innovative medicines, ii) industry's capacity to innovate and iii) Member States' ability to improve the value and effectiveness of healthcare spending.

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[1] Creating an Innovative Europe: Report of the Independent Expert Group on R&D and Innovation appointed following the Hampton Court Summit and chaired by Mr. Esko Aho, 2006. Available at: http://ec.europa.eu/invest-in-research/action/2006_ahogroup_en.htm

[2] White Paper on Public Procurement of Biological Medicines. EuropaBio. 2015. Available at: http://www.europabio.org/sites/default/files/europabio_white_paper_on_public_procurement_of_biological_medicines_final.pdf

[3] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts. Available at: http://eur-lex.europa.eu/legal-content/en/TXT/?uri=celex:32004L0018

[4] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.094.01.0065.01.ENG

[5] Hatzopoulos V and Stergiou H. Public Procurement Law and Health care: From Theory to Practice Research. Paper in Law Cahiers juridiques No 2 / 2010. Available at: https://www.coleurope.eu/system/files_force/researchpaper/research_paper_2_2010_hatzopoulos.pdf?download=1

EuropaBio members welcome the following provisions of the new EU public procurement directive as regards the promotion of innovation-friendly public procurement:

- **Simplification of procedures:** Directive 2014/24/EU takes over a number of simplified rules and procedures from Directive 2004/18/EU such as a negotiated procedure without prior publication and introduces new processes, including an Innovation Partnership – to fill innovation gaps in the market.

  - Negotiated procedure without prior publication: This procedure without publication of a contract notice remains an exceptional one and shall be used only in cases where the specific circumstances as defined in Directive 2014/24/EU such as reasons of urgency brought about by circumstances external to the Contracting Authority. While Directive 2014/24/EU provides that this procedure is to be used in exceptional circumstances, it was used by some Belgian public hospitals, especially in the Flemish region, for the purchase of patented "erythropoiesis-stimulating agents" (WHO ATC Code B03XA). This application of the negotiated procedure without prior publication to healthcare products should be carefully considered in light of the conditions laid out in the legislation.

  - Innovation partnership: used to fill innovation gaps, this is a promising tool whereby the contracting authority issues a procurement call by only identifying the need for an innovative product that does not exist on the market. Through this new mechanism, it is hoped that innovation will spur contracting authorities to achieve value for money and deliver environmental and societal benefits through procurements.

- **More comprehensive award criteria:** by clearly recommending the "Most Economically Advantageous Tender" (MEAT) criterion, public authorities are requested to place more emphasis on quality (including technical merit, aesthetic and functional characteristics, accessibility, design for all users), environmental considerations, social aspects, after-sales services, technical assistance and delivery conditions (such as delivery date, delivery process, etc.) in particular taking into account the price and life-cycle cost of what is procured (Art. 68 of new PP Directive). An effective assessment of value may be necessary and should go beyond price.

  - With the reinforcement of the MEAT criteria in the new Directive, the best value for money can be achieved by taking into account common societal goals. However, an increased effort in terms of communication is required to allow payers to be able to support the complexity of tenders based on the MEAT criteria.

- **Benefits for Small and Medium Size Enterprises (SMEs):** the revised rules facilitate the access of SMEs to public procurement, for instance by dividing contracts into lots and by reducing administrative requirements for participation.

- **Sound procedures and governance:** Member States are asked to ensure that the procurement procedures are transparent and properly monitored, with an implementation report transmitted to the European Commission (EC) every three years.

3. DEFINITION OF "BUYING INNOVATIVE" IN THE AREA OF BIOLOGICAL MEDICINES

With regard to the healthcare biotechnology sector "buying innovative" means organising a public procurement process in a way that ensures a balance between the various public health objectives, i.e. securing access for patients to innovative therapies, guaranteeing high standards of quality, safety and efficacy of products purchased, and incentivising companies to compete in a free and dynamic internal market. More specifically in a way that:

- Reflects patients' needs and offers freedom of choice for doctors/patients, by ensuring that treatment options are not limited and decisions can always be made by a physician in consultation with patients. Given the recognised differences between biological medicines, a variety of biological medicines[6] should be available for patients, not only a single medicine.

- Respects physicians' prescribing authority as regards decisions to keep treated patient with their current treatments or to alternate therapies. The decision to switch a patient to a new product should only be taken by the prescribing doctor in alignment with the patient and not be based on the results of a tendering process or purely on economic considerations.

[6] What is different about biotech treatments, EuropaBio Fact Sheet. Available at: http://www.europabio.org/what-different-about-biotech-treatments

- Takes into account the complexity of biological medicines, including manufacturing practices, and for instance allows for sufficient lead times between an award decision and product delivery.

- It is awarded based on careful consideration of additional criteria besides price, such as manufacturer experience, long-term efficacy and safety data, the need to ensure continuity of treatment, quality, services, manufacturing and reliability of supply as well as outcomes and additional potential costs (e.g. hospitalisations) incurred by patients and healthcare professionals during the course of previous therapeutic plans.

- Fosters fair market competition and innovation, for instance by ensuring all manufacturers are able to compete with other bids and/or negotiate with payers on an equal footing.

4. WHY BUYING INNOVATIVE? WHAT DOES IT MEAN FOR PATIENTS AND FOR INDUSTRY?

There are two fundamental reasons why an innovation-driven public procurement framework is beneficial to society and should be further promoted.

First of all, **buying innovative can create long term savings for the healthcare system as a whole**.

- By introducing new mechanisms of action and targeting new receptors, new and innovative medicines bring efficiencies in a number of areas related to the management of disease and the well-being of patients, which in the long term can accrue to significant savings for national healthcare systems[7,8].

- Examples of such savings are: reduced consumption of facilities in hospitals[9], reduced time commitments of specialist physicians, a labour force that is generally less sick and more productive, etc. These are sometimes also known as "Life-Cycle Costing" (LCC) of biological medicines, meaning all the costs and savings that will be incurred during the lifetime of the product (see more examples in Box 1 below).

- LCC is a tool which evaluates the costs of an asset throughout its life-cycle. Often based on a purely financial valuation, LCC should be based on methodologies that assess the price/quality ratio more comprehensive by, for example, considering additional benefits for patients and society as a whole.

- Health Technology Assessments (HTAs) could serve as a basis for LCC and for defining the best price/quality ratio however the application of HTAs in the public procurement process has been inconsistent to date.

Secondly, **buying innovative is an incentive for innovation by indirectly fostering investments in future research and development (R&D).**

- Due to their inherent scientific and manufacturing complexity, the development of biological medicines is a very risky endeavour and it requires significant initial financial investment[10] in order to be sustained.

- Healthcare financing and market access policies – i.e. the framework of policies and laws at the gateway between manufacturers and end-users, including all rules related to pricing, reimbursement and public procurement – are often quoted by experts as the most significant business challenges and strongly affect overall attractiveness of a given market[11].

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[7] Towse A, Diego D, Veenstra D, Carlson J and Garrison L. Understanding the Economic Value of Molecular Diagnostic Tests: Case Studies and Lessons Learned. J. Pers. Med. 2013, 3(4), 288-305

[8] Trusheim M, Berndt E and Douglas F. Stratified medicine: strategic and economic implications of combining drugs and clinical biomarkers. 2007, Nature Reviews Drug Discovery 6, 287-293

[9] Epstein RS, Moyer TP, Aubert RE, O Kane DJ, Xia F, Verbrugge RR, Gage BF, Teagarden JR. Warfarin genotyping reduces hospitalization rates results from the MM-WES (Medco-Mayo Warfarin Effectiveness study). J Am Coll Cardiol. 2010 Jun 22;55(25):2804-12

[10] Khanna I. Drug discovery in pharmaceutical industry: productivity challenges and trends. Drug Discovery Today, Volume 17, Issues 19–20, October 2012, Pages 1088-1102

[11] Taylor RS, Drummond MF, Salkeld G and Sullivan SD. Inclusion of cost effectiveness in licensing requirements of new drugs: the fourth hurdle. BMJ. 2004 Oct 23; 329(7472): 972–975.

BOX 1

LONG TERM SAVINGS OF BUYING INNOVATIVE: THE HAEMOPHILIA EXAMPLE

Haemophilia is a rare genetic bleeding disorder affecting people who are congenitally deficient in one of the blood clotting proteins necessary for clot formation. As a life-long and life threatening disease, haemophilia confers significant burden on to the patient, the patient's family, and the health care system. Patients treated episodically, mainly because of poor availability of coagulation factor concentrates, suffer from frequent spontaneous bleeding particularly in joints and muscles which may lead to long-term damage. Such bleeding events can make large demands on the healthcare system including expensive additional therapy like joint replacements.

Today the usual treatment for haemophilia is replacement of the missing coagulation proteins to control and primarily prevent bleeding (on demand therapy). Prophylaxis, i.e. regular infusion of the deficient clotting factor concentrates in order to prevent bleeding, is the ideal treatment for people with severe haemophilia, and it has demonstrated efficacy in older children and adult patients[12]. Studies show that patients receiving prophylaxis have significantly fewer days lost from work or school, as well as fewer days spent in hospital ($p<0.01$) compared to on-demand treatment[13]. Similarly, research shows joint bleeding can have a negative impact on academic achievement in children[14].

Procurement practices providing for prophylaxis instead of on demand treatment can reduce healthcare expenditure linked to joint replacements and reduce long term societal costs linked to school/work absenteeism and academic achievement. Studies have shown that, subject to continuing clinical evidence of the effectiveness of pharmacokinetic dosage and the role of prophylaxis in decreasing inhibitor incidence, treatment for life with prophylaxis is a cost-effective therapy using current criteria for the reimbursement of health care technologies in a number of countries (e.g. UK and Sweden)[15].

[12] Manco-Johnson MJ, Kempton CL, Reding MT, et al. Randomized, controlled, parallel-group trial of routine prophylaxis vs. on-demand treatment with sucrose-formulated recombinant factor VIII in adults with severe hemophilia A (SPINART). J Thromb Haemost. 2013;11:1119-27.

Collins P, Faradji A, Morfini M, et al. Efficacy and safety of secondary prophylactic vs. on-demand sucrose-formulated recombinant factor VIII treatment in adults with severe hemophilia A: results from a 13-month crossover study. J Thromb Haemost. 2010; 8:83-9.

[13] Aledort LM, Haschmeyer RH, Pettersson H. A longitudinal study of orthopaedic outcomes for severe factor-VIII-deficient haemophiliacs. The Orthopaedic Outcome Study Group. J Intern Med. 1994;236:391-9.

[14] Shapiro AD, Donfield SM, Lynn HS, et al. Defining the impact of hemophilia: the Academic Achievement in Children with Hemophilia Study. Pediatrics. 2001;108:E105.

[15] Farrugia A, Cassar J, Kimber MC, Bansal M, Fischer K, Auserswald G, O'Mahony B, Tolley K, Noone D, Balboni S., Treatment for life for severe haemophilia A- A cost-utility model for prophylaxis vs. on-demand treatment, Haemophilia. 2013 Jul;19(4):e228-38. doi: 10.1111/hae.12121. Epub 2013 Mar 28.

5. PRO-INNOVATION PRINCIPLES FOR PUBLICLY PROCURING BIOLOGICAL MEDICINES

Biological medicines are usually procured by pharmacies at hospital level, prescribed by qualified physicians, delivered by expert nurses under medical vigilance (often by treating physicians) and subject to additional regulatory requirements relating to pharmacovigilance legislation[16].

As they are innovative and complex products addressing complex health conditions, it is important that the following basic principles are considered by purchasing authorities when it comes to biological medicines:

- **Multi-disciplinary approach:** when defining the needs of the market and developing technical tender criteria, purchasing authorities should be supported by clinical experts, health economists and patients. Ideally, an expert committee including all this expertise should be brought together in a tendering committee to define the right clinical criteria of each tender. Given that biological medicines often provide therapeutic solutions for diseases where no other treatment exists (as is the case for many rare diseases), a multi-disciplinary evaluation committee is necessary in the evaluation/award phase to deal with the sometimes complex comparative exercises of the different bids. The tender evaluators should be trained in how to assess compliance, especially with respect to the innovative tender criteria.

- **Homogeneity of tendering lots:** if the practice of public procurement is to foster innovation in the healthcare biotech sector, the bundling of on- and off-patent biological medicines in a single tender should be avoided. Numerous on-patent products should be considered as a tool to incentivise innovation and ensure sustainable market conditions.

- **Competition:** calls for tenders should be designed in such a way as to guarantee fair competition between all potential suppliers. Discrimination against originator manufacturers is often counterproductive and should be avoided. In the same context, the participation of Small and Medium Size Enterprises (SMEs) should be fostered where possible.

- **Transparency:** tender opportunities and the procurement decision-making process should be widely advertised to ensure transparency and to avoid any risk of favouritism or arbitrariness on the part of the contracting authority. Contracting authorities have the obligation to inform unsuccessful tenderers of the reasons for rejecting their tenders. The definition of eligibility criteria and the decision-making process leading to the award decision should be a critical feature of every tendering process. It is also the responsibility of contracting authorities to specify and publish the criteria for awarding the contract and the relative weighting given to each of those criteria in advance and in time for tenderers to be aware of them when preparing their tenders.

- **Most Economically Advantageous Tender (MEAT):** MEAT award procedures mean that a whole range of criteria – and not only price – is taken into account when evaluating the proposals, thus making it possible to award the optimal combination of life-cycle costs and quality considerations (cf. examples of the MEAT criterion on pp 8-9). By applying the MEAT criterion to medicines, authorities can transition towards a form of procurement based on better outcomes for patients and healthcare systems.

6. THE IDEAL PROCUREMENT PROCESS FOR BIOLOGICAL MEDICINES

A. CHOOSING THE PROCEDURE

The preparatory stage of any procurement procedure is crucial. For pro-innovation public procurement of biological medicines, a restricted procedure or negotiated and competitive dialogues are the best solutions.

- In a **restricted procedure** (see Article 65 of Directive 2014/24/EU) contracting authorities can assess technical capacity at a prior stage and also manage the number of operators they invite to tender. This staggered procedure may help contracting authorities determine the appropriate level of clinical performance to aim for within their specifications, award criteria and contract performance clauses. Purchasing authorities should engage with bidders in preliminary

[16] Leopold C, Habl C, Vogler S and Favry L. Tendering of Pharmaceuticals in EU Member States and EEA countries: Results from the country survey; 2008; ÖBIG Forschungs- und Planungsgesellschaft mbH

market discussions to better evaluate the potential offers. An **early dialogue** would also ensure that, under the right conditions, the purchasing authorities accessany potential commercially confidential information which they may later need to review the different offers. Finally, such a dialogue may help to assess the constraints on manufacturing and supply capacity for a tender – this is especially true in the field of vaccination where the manufacturing process (and therefore lead times) can be particularly complex. **This procedure is particularly recommended for patented biological medicines.**

- **'Negotiated and competitive dialogue' procedures** can be used by public authorities in special circumstances (see Article 65 of Directive 2014/24/EU). Competitive dialogue may be particularly efficient for complex procurements as biological medicines, for instance where a contracting authority is not fully able to define the technical means that would fulfil its needs. In deciding which procedure to use, it is useful to have some knowledge of the market – e.g. the availability, cost and possible practical implications of alternative modes of action for the same type of products. A dialogue with potential suppliers prior to tendering would allow authorities to reach a more detailed picture about the market. This allows the selected participants to propose solutions which can then be refined in successive stages leading to selection of the most economically advantageous tender (MEAT). **This procedure is particularly recommended for off-patent biological medicines.**

B. DEFINING THE TECHNICAL CRITERIA OF THE CONTRACT

Once authorities have defined the subject of the contract, this needs to be expressed in measurable technical specifications which are included in the contract notice or tender documents. Technical specifications have two functions:

- They describe the contract against the current state of market so that companies can decide whether it is of interest to them. In this way they help determine the level of competition.

- They provide measurable technical criteria against which bids will be evaluated. They constitute minimum compliance criteria. If they are not clear and accurate, they will inevitably lead to unsuitable offers which will ultimately be rejected.

Technical specifications for biological medicines should always be formulated by reference to existing specific product labels which defined the detailed conditions of usage for a product. In the EU, the marketing authorisation of biological medicines is granted by the European Commission (EC) on the basis of a robust quality, safety and efficacy assessment by the European Medicines Agency (EMA). The EMA provides extensive information on the products they assess, including through European Public Assessment Reports (EPARs[17]). The label provided by European regulatory authorities should be the basis for the definition of technical specifications. National medicine regulatory authorities can also provide additional information on the characteristic of products to be procured. It is recommended that a representative of this authority is a member of (or an adviser to) the expert committee responsible for managing the procurement process.

[17] European Public Assessment Report, European Medicines Agence. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124

Purchasing authorities often use the World Health Organisation Anatomical Therapeutic Chemical[18] (ATC) classification system to define the category or specific biological product to be purchased. The ATC classification attributes codes to all pharmaceutical substances according to the organ or the system on which they act. The classification includes 5 groups levelled from a broad category (level 1, e.g. medicines treating cardio-vascular diseases) to specific substances (level 5, e.g. metformin). When using ATC codes at level 1 to 4 to identify the products they wish to purchase, authorities are likely to bundle products that do not share the same quality, safety and efficacy attributes in the same lot. Only ATC code at level 5 should be used to ensure that products that meet the specifications of the tender are purchased.

In many cases "performance-based" (or "functional specifications") may be most appropriate to identify the type of specifications for biological medicines. A performance-based specification would describe the desired result and which outputs (for example in terms of quality, quantity, and reliability) are expected, including how they will be measured. It would however prescribe neither which inputs nor which work method the tenderer should provide. This presents the following advantages for both parties:

- The tenderer is free to propose the most appropriate solution, according to its creativity and it might even be challenged to propose innovative technical solutions.

- Purchasing authorities simply have to define the therapeutic indications (or disease areas) where their needs lay, making it easy to split the tenders into multiple lots, leaving it to prescribers, in alignment with the patients, to make the final decisions based on the recorded clinical history of each individual.

However, when setting performance-based specifications, authorities should think carefully about how to assess and compare tenders in a fair and transparent way. They may ask the tenderer to indicate how the desired result will be achieved and meet the level of quality specified in the bidding documents. Contract performance clauses, e.g. reassessment based on clinical outcomes gathered through real world data, might be one of the available options.

BOX 2

Best Practice Case Study
Definition of the tender criteria of the contract in Czech Republic, Poland and the UK

A recent analysis[19] of the award criteria used by purchasing authorities to grant public tenders of pharmaceutical products reveals that a vast majority of authorities still rely on the lowest bid as a primary criterion. In countries such as Czech Republic and Poland, the weighted value of the lowest price compared to all award criteria is 70% and 50% respectively.

However, some national purchasing authorities recommend the inclusion of outcomes-based procurement as primary criteria. In the United Kingdom (UK), the use of quality criteria is encouraged throughout commissioning practices in the National Health System (NHS). Indeed the NHS is currently aiming for more consistent tendering with more outcomes-focused award criteria such as more emphasis on clinical outcomes data and long term value alongside commercial considerations[20]. According to the NHS Confederation, outcomes-based commissioning has the following benefits:

- It is a way of paying for health and care services based on rewarding the outcomes that are important to the people using them;

- It typically involves the use of a fixed budget for the care of a particular population group, with aligned incentives for care providers to work together to deliver services which meet outcomes; and

- It aims to achieve better outcomes through more integrated, person-centred services and ultimately provide better value for every euro spent on health and care.

[18] http://www.whocc.no/atc/structure_and_principles/

[19] Martens M. and Carbonnelle N. White Paper: Public procurement of medicinal products: Common legislation but diverging implementation approaches throughout the EU. Bird & Bird. Available at: http://www.twobirds.com/~/media/PDFs/White%20Papers/Public%20Procurement%20of%20Medicinal%20Products.pdf

[20] Outcomes-based commissioning. NHS Confederation. 2014. Available at: http://www.nhsconfed.org/health-topics/commissioning/outcomes-based-commissioning

Outcomes-based procurement is not without challenges as it requires:

- Defining the desired outcomes in a new way: outcomes-based procurement articulates tender criteria in the form of end goals without specifying exactly how these are to be achieved. The challenge is to balance the level of tender specifications so that patients' criteria are understood, and the level of freedom and creativity left to the potential providers[21]. Healthcare needs can be particularly challenging to identify as they are often perceived differently between stakeholders (in particular from a patient perspective);

- Measuring performance in an objective, measurable, clear and realistic way: the challenge is for the public authority to provide comprehensive, accurate and robust data to reach agreement with a potential provider on appropriate performance standards; and

- Pricing according to performance: in this context, the key principle of pricing models should be to establish the right incentives for potential providers to encourage the desired outcomes. Prices should not be calculated on the basis of a transactional pricing model, but should be tied to achievement of the agreed outcomes.

C. EVALUATING TENDERS

A whole range of award criteria can be taken into account when evaluating the proposals by manufacturers of biological medicines, making it possible to award the optimal combination of overall long-term costs and quality considerations.

While price still remains a criterion that public authorities can use, the evaluation of suppliers' bids should be carefully pondered to balance price and quality criteria. In the case of biological medicines, which are complex products and are not deemed interchangeable, price should not constitute the main criteria to award a contract. Quality attributes, such as efficacy, safety, quality, supply security or timely manufacturing capability, should constitute at least 50% of the scoring system.

In addition, purchasers should include other components associated with the Life-Cycle Costing (LCC) of the product and the potential benefits it can bring patients and society as a whole. For example, this includes how the purchased product can help to avoid unnecessary hospitalisation, or to foster the return of patients to an active life. The overall long-term costs of biological medicines largely depend on the standard of care in each particular therapeutic area and this is why they might significantly change if the standard of care evolves over time. A holistic approach, considering environmental as well as social aspects, should be pursued.

When all the above conditions are considered, the product with the lowest purchase price may not always prove to be the most financially advantageous in the long term, the most innovative or the most effective to improve patient health outcomes.

BOX 3

Best Practice Case Study in Denmark
Statens Serum Institute: applying the MEAT criterion in vaccine tenders

Since 1902, the Danish Statens Serum Institut (SSI) is responsible for research-based health surveillance, rational use of IT and prevention and control of infectious diseases, biological threats and congenital disorders in the Danish healthcare system. The SSI is a public enterprise of the Danish Ministry of Health[22].

One of the main activities of the SSI is to ensure the supply of vaccines, other biological products and diagnostic services through production and public procurement. Unlike other tender processes for medicines, for this lot the SSI adopts the Most Economically Advantageous Tender criterion to select the winner. It is crucial that the purchasing system rewards the intrinsic value of the vaccination, considering the long term impacts of this system on the performance and the sustainability of the vaccination programme for the population.

[21] Are we ready for what outcomes based commissioning might mean? 2014. Available at: http://www.capita.co.uk/news-and-opinion/opinion/2014/outcomes-based-commissioning-in-the-nhs

[22] Statens Serum Institut (SSI). Available at: http://www.ssi.dk/English/Service/AboutSSI.aspx

In 2015 the SSI tender for Human papillomavirus (HPV) vaccines included a number of weighted factors for assessing the various bidders. Several types of cancer are associated with HPV, most notably cervical cancer[23].

Weighted factors were considered as follows:

- 35% efficacy of the vaccine (assessed based on approved indications and protection against all types of HPV related cancers and pre-cancerous lesions);
- 30% risk of adverse effects (assessed based on their nature and frequency); and
- 25% price (calculated as fixed price per dose in multi packaging);
- 10% efficacy against condylomas (co-morbidity).

Efficacy and risk were assessed based on Summary of Product Characteristics (SPC) and European Public Assessment Report (EPAR) at the time of tender submission. The final additional 10% factor (efficacy against condylomas) was decided by the SSI as it was deemed an important characteristic to adequately rate the clinical profile of the vaccines.

If properly applied, the system introduced by the SSI ensures that the winner of the tender is the best possible treatment from a population perspective rather than merely the cheapest one. This should be beneficial to patients, public health authorities, industry and payers as the awarded product is also likely to be the most economically advantageous in the long term, while providing the best collective medical added value. It is important to note that this system can nevertheless lead to totally paradoxical outcomes if a very low price is offered that annihilates all value criteria. Aspects like programme continuity/acceptance, local research & development could be added to tender criteria.

[23] http://www.cdc.gov/hpv/cancer.html

BOX 4

Best Practice Case Study in Ireland
Applying the MEAT criteria in haemophilia tenders

In Ireland tenders for Haemophilia A are generally awarded using the following Score Sheet.

SCORE SHEET: PRODUCT SELECTION & MONITORING ADVISORY GROUP FACTOR VIII		
SCORING CRITERIA		**TOTAL MARKS AVAILABLE**
PHASE 1		
SAFETY	Human Albumin in Culture Medium	15
	Additional Human or Animal Protein (e.g. monoclonal antibodies)	5
	Viral Inactivation	10
	Inhibitors	40
	Prion Removal	5
	Other Adverse Events	10
	Total for Safety	**85**
EFFICACY	Recovery/Half Life (adult/paediatric)	12
	Clinical Response (adult/paediatric)	25
	Total for Efficacy	**37**
QUALITY	Stability	9
	Volume of Administration	5
	Instructions for Use & Handling	5
	Ease of Administration	6
	Application of Unique Bar-Code	5
	Total for Quality	**30**
SECURITY OF SUPPLY / AVAILABILITY	Number of Manufacturing Plants	4
	Security of Supply	6
	Total for Supply/ Availability	10
	Clinical Opinion	2
	Consumer Opinion	2
	Tender	2
	Total for Scientific Support	**6**
Total Scores Awarded: Phase 1		**168**
PHASE 2		
COST	**Total For Cost**	**60**
Total Scores Awarded: Phase 2		**228**

The above Score Sheet is considered among best practices at a global level for public procurement of innovative products in this specific therapeutic indication. The Sheet is however also a concrete example of how MEAT criteria can be implemented in daily practice by purchasing authorities. By providing separate and detailed weights to categories such as safety, efficacy, quality and security of supply on top of price, the sheet enables public authorities to better capture the relevant patient-outcomes, product utilization, suppliers' strengths and the opinion of experts on quality aspects. In the long run, this should enable healthcare systems to procure medicines based on the actual outcomes and the life-cycle benefits generated by new and innovative medicinal products.

7. PROMOTING SMES' PARTICIPATION IN PUBLIC PROCUREMENT

Between 2009 and 2011, an estimated 56 percent of all public procurement contracts above the EU-thresholds were awarded to Small and Medium-size Enterprises (SMEs). This corresponds to a 29% market share. But SMEs are somewhat underrepresented in public procurement compared to their overall weight in the economy. In the same period, the 29% share of European SMEs is 29% points lower than it would have been (58%) if the share of public procurement they won equalled their share of the total gross value added for the European economy. In the pharmaceutical sector, SMEs rarely win contracts concerning medical products[24].

Provisions giving SMEs greater access to public procurement by reducing the cost and/or burden of participating are crucial for the healthcare biotech sector and for the EU economy as a whole. As over 40% of all new innovative medicines in Europe originate from SMEs[25] , it is very important to promote SMEs' participation in public procurement. That can be achieved, for example, by:

- Ensuring, where possible, that the size of the contract is not an obstacle in itself to participation by SMEs;
- Giving sufficient time to prepare bids;
- Ensuring timely payments, for instance by e-procurement tools (e.g. e-signatures and secured web platform where to submit tender proposals);
- Setting proportionate qualification and economic criteria; and
- Dividing contracts into lots.

BOX 5

Best Practice Case Study in Ireland
Promoting SMEs' participation in tenders

While case studies on SMEs' participation in healthcare public procurement are scarce, a large of number of EU Member States has made their participation a priority of their public procurement practices. This is the case of Ireland's reforms on public procurement and is consistent with the country's aspiration of being a knowledge-based economy[26].

In 2010 and in the midst of an economic recession, the Irish government adopted a series of reforms in public procurement focusing on ways to facilitate SME participation in competing for public sector contracts. These reforms – which included inter alia lowering thresholds for the advertising of calls on a national e-procurement portal and ensuring financial and insurance capacity criteria are proportionate to the value of the contract – were intended to act as incentives for companies which were contending in an environment characterised by low domestic demand and reduced availability of capital.

[24] SMEs' access to public procurement markets and aggregation of demand in the EU. European Commission. 2014. Available at: http://ec.europa.eu/internal_market/publicprocurement/docs/modernising_rules/smes-access-and-aggregation-of-demand_en.pdf

[25] Helene Lincker, Constantinos Ziogas, Melanie Carr, Nuria Porta, Hans-Georg Eichler, Regulatory watch: Where do new medicines originate from in the EU?, Nature Reviews Drug Discovery 13, 92–93 (2014) doi:10.1038/nrd4232

[26] Anthony Flynn A, Davis P, McKevitt D and McEvoy E. Sustainable Public Procurement in practice: Case study evidence from Ireland. 2015. In: Albano, Gian Luigi and Snider, Keith F. and Thai, Khi V., (eds.) Charting a Course in Public Procurement Innovation and Knowledge Sharing. PrAcademic Press, Boca Raton, Florida. Available at: http://ippa.org/jopp/download/vol12/Book/Chapter%206_Flynn_et_al.pdf

In 2011, the Kilkenny Local Authorities (KLA) in Ireland underwent an assessment of the supply of their water and waste water services maintenance and embarked into a new tendering of these services. Supported by a multidisciplinary group of experts (the procurement unit) working closely with the official Water Services, KLA developed policy guidelines for facilitating small suppliers' access to the market. From the outset, the Procurement Unit was mindful not to overload the contract specifications and advertised it on www.etenders.gov.ie (Ireland's national portal for public sector contract opportunities). The tender was also divided in four different lots allowing smaller suppliers to compete.

Over time, the reorganisation of the water services resulted in a €120,000 in savings and in a long-term framework agreement supporting four local, small suppliers. This demonstrates that internal procurement objectives can also foster sustainable economic and social outcomes. While the extrapolation of this example should be done carefully, there are similitudes with the healthcare sector and a number of the principles and approaches described above can be applied to the procurement of biological medicines.

BOX 6

Best Practice Case Study in Germany
Promoting SMEs' participation in medicines' tenders

In Germany the largest sick fund is AOK, which covers around 30% of the total population with social and health insurance. AOK is in turn made up of 11 regional AOKs. The AOK from Baden-Wuerttemberg runs several national tenders on behalf of all other AOKs. As AOK Baden-Wuerttemberg awards the majority of procured products with a winner-takes-all approach the volumes can be significant. To allow SMEs to successfully participate in these tenders, AOK Baden-Wuerttemberg has divided the national tenders in 7 different regional lots, which get awarded individually, allowing SMEs to compete and be able to supply markets that are commensurate to their (limited) production capacity.